TERUMO

K092644

DEC 10 2009

Section 5
510(k) Summary (for FDA Website Presentation)

Submitter Information:
This submission was prepared in August 2009 by:

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This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo Pressure Isolator	Transducer, Blood Pressure, Extravascular (Code: DRS)	Transducer Isolator

Predicate Device(s):
Terumo Cardiovascular Systems has identified the IBC Isolator (Model 2000N) as an appropriate predicate device for which comparisons of the new Terumo device shall be demonstrated. The IBC Isolator is manufactured by International Biophysics Corporation and is legally marketed under 510(k) application K841959. The 510(k) application was originally sponsored by Sterile Design, Incorporated in Oldsmar, Florida with an FDA decision date of October 19, 1984.

Summary:
The Terumo Pressure Isolator is a single use, disposable device that is intended to act as an interface between the extracorporeal circuit and a pressure gauge in order to prevent fluids from coming into contact with gauges while transducing pressure during cardiopulmonary bypass procedures. The device is geometrically similar to the IBC Isolator device, which is the predicate device for purposes of this application. Furthermore, the operating principles and product technology of the two devices are identical.

The primary differences between the Terumo Pressure Isolator and the predicate IBC Isolator are herein identified as material differences, specific dimensions of the components and the type of diaphragm material that is encapsulated within the device housing.

The Terumo Pressure Isolator has a housing that is made of rigid polyvinylchloride and the predicate IBC Isolator is comprised of polycarbonate. Both of these materials permit a clear view of the fluids that enter the isolator, although the polycarbonate housing is clearer than the polyvinylchloride housing. This difference would not be problematic in an operating arena and neither device offers a therapeutic and/or functional advantage as a result of materials used and or housing clarity.

From the perspective of product geometry, the Terumo Pressure Isolator is designed with a more rounded housing as compared to the IBC Isolator, which is characterized by more distinct edges at the opposing ends of the housing chamber. It is expected that the rounded design featured by the Terumo Pressure Isolator will facilitate enhanced fluid flow and would be less susceptible to fluid becoming stagnated within the chamber.

Finally, the Terumo Pressure Isolator includes a flexible polyvinylchloride diaphragm inside the housing chamber, whereas the predicate IBC Isolator includes a polyurethane diaphragm. This difference in materials does not create any functional advantages for either device as both materials are capable of transducing circuit pressures to gauges that would be at the distal end of the pressure circuit.

With respect to product performance, Terumo conducted head-to-head studies to assess the relative functional capabilities of the Terumo Pressure Isolator to the predicate IBC device. The studies included a tubing connection test (pre-connection with solvent as well as testing without a solvent bond) whereby the strength of the connection between circuit tubing and the device was measured – and the resulting conclusion is that there is no difference.

Testing also included a pressure transduction assessment to ascertain if the Terumo Pressure Isolator was capable of accurately and consistently transferring circuit pressures to gauges at a distal point in the pressure monitoring circuit. Again, the Terumo device was noted to be functionally equivalent to the predicate device.

Terumo Cardiovascular also conducted a mechanical integrity assessment in the form of leak test where both negative and positive pressures were applied to the isolator and the devices were examined for evidence of breach. The Terumo device and the predicate device were found to be equivalent.

Additional Safety Information:

- Sterilization conditions for the Terumo Pressure Isolator are validated to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.
- Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo Pressure Isolator is *substantially equivalent* to the predicate IBC Isolator device. It is further concluded that any recognized differences noted during the assessments do not raise any new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 10 2009

Terumo Cardiovascular Systems Corp.
c/o Mr. Garry A. Courtney
Regulatory Affairs
125 Blue Ball Rd.
Elkton, MD 21921

Re: K092644
Trade Name: Terumo Pressure Isolator
Regulation Number: 21 CFR 870.2850
Regulation Class: Class II (two)
Product Code: DRS
Dated: October 15, 2009
Received: October 16, 2009

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

Section 4
Indications for Use

510(k) Number (if known): ~~Unknown at time of submission~~ K092644

Device Name: Terumo Pressure Isolator

Indications for Use:
The pressure isolator is a single use, disposable device that is intended to act as an interface between the extracorporeal circuit and a pressure gauge in order to prevent fluids from coming into contact with gauges while transducing pressure during cardiopulmonary bypass procedures. The device may be used in procedures lasting up to 6 hours in duration.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)

OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092644